UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,847	08/01/2003	Toshiyuki Kohara	2003_1088A	1043

513 7590 09/30/2004

WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER	
AULAKH, CHARANJIT	
ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/631,847	KOHARA ET AL.	
	Examiner	Art Unit	
	Charanjit S. Aulakh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-31 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-31 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 2.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-31 are pending in the application.

Specification

2. The disclosure is objected to because of the following informalities: Page 333 of specification needs to be replaced since the text is not straight.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 26-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating diabetes and Alzheimer disease, does not reasonably provide enablement for preventing diabetes and Alzheimer disease or treating/preventing all other diseases mentioned in claims 26-31. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The following eight different factors (see Ex parte Foreman, 230 USPQ at 547; Wands, In re, 858.F. 2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed:

Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the

breadth of claims. In the instant case, the specification is not enabling based on atleast four of the above mentioned eight different factors such as quantity of experimentation necessary, presence of working examples, the state of the prior art, the amount of direction or guidance provided and the breadth of claims.

The instant compounds are inhibitors of glycogen synthase kinase-3 beta (GSK-3beta) and therefore, will have utility in treating only disease conditions where hyperactivity of GSK-3beta is well known in the prior art to be involved in the etiology of specific disease conditions such as diabetes and Alzheimer. Hyperactivity of GSK-3beta is one of the several other known mechanisms responsible for the etiology of diabetes and Alzheimer disease and therefore, the instant compounds will have utility in treating but not preventing these diseases. There is no teaching either in the specification or prior art that hyperactivity of GSK-3beta is implicated in all known neurodegenerative diseases, alopecia, cancer, diabetic complications or diseases due to malfunction of immune system. There are no working examples present to show efficacy of instant compounds in known animal models of all known neurodegenerative diseases, alopecia, cancer, diabetic complications or diseases due to malfunction of immune system. There is no direction provided how the instant compounds having inhibitory activity at GSK-3beta will have utility in treating all known neurodegenerative diseases, alopecia, cancer, diabetic complications or diseases due to malfunction of immune system. The instant compounds of formula (I) encompasses several hundreds of thousands of compounds based on the value of variables R0, R1, R2, R3, R4 and R5 and therefore, in absence of such teachings, guidance or working examples, it would

require undue experimentation to demonstrate the effectiveness of instant compounds in known animal models of all known neurodegenerative diseases, alopecia, cancer, diabetic complications or diseases due to malfunction of immune system and hence their utility for treating these disease conditions.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1-31, the term ---optically active form --- is indefinite since it is not defined. It is of note that the instant compounds of formula (I) encompasses several hundreds of thousands of compounds and therefore, it is not clear which form of each of these compounds will be optically active?

In claims 1, 2 and 12, for the value of variables R3 (5, 6 and 7) and R5, the term ---a group derived from---is redundant and is not needed.

In claims 20, 21 and 26-31, the term ---medicament--- is vague. The applicants are suggested to use the term ---A pharmaceutical composition---.

Claims 20 and 21 appear to be duplicates of claims 22 and 23. What is the difference between these claims?

In claims 26-31, the term ---prevention----is indefinite since the degree of prevention (20%, 40%, 60%, 80% or 100%) is not defined and furthermore, how this prevention is being assessed?

In claim 26, the term –a disease caused by glycogen synthase kinase-3 beta hyperactivity--- is indefinite since specific diseases are not defined.

Claims 26-31 provide for the use of medicament, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 26-31 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, 4, 5 and 20-31 are rejected under 35 U.S.C. 102(b) as being anticipated by De Wald (U.S. Patent no. 3,790,576, cited on applicant's form 1449).

De Wald discloses Pyrazoloquinolines having antidepressant activity. The compounds disclosed (see claim 1 as well as examples) by De Wald anticipate the instant claims when R4 and R5 together form a carbocyclic ring in the instant compounds of formula

(I). It is of note that instant claims 20-31 are directed to pharmaceutical compositions and not method claims and therefore, are anticipated by De Wald's reference.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

C. S. Aulakh

Charanjit S. Aulakh
Primary Examiner
Art Unit 1625